CLAIMS

What is claimed is:

1. An oral controlled release pharmaceutical composition having a controlled release core, said core comprising:

a) a therapeutically effective amount of at least one pharmaceutically active ingredient;

b) an optional surface active agent;

c) an optional pharmaceutically acceptable alkaline agent; and

d) at least one water soluble binder and at least one water insoluble binder;

wherein the controlled release is achieved by way of the water soluble and water insoluble binders.

2. The composition of claim 1, further comprising a single layer of coating on said core, said coating comprising an enteric coating agent.

3. The composition of claim 1 wherein the pharmaceutically active ingredient is selected from analgesics, anti-inflammatory agents, antihelminthics, anti-arrhythmic agents, anti-bacterial agents, anti-viral agents, anti-coagulants, anti-depressants, anti-diabetics, anti-epileptics, anti-fungal agents, anti-gout agents, anti-histamines, anti-hypertensive agents, anti-malarials, anti-migraine agents, anti-muscarinic agents, anti-neoplastic agents, erectile dysfunction improvement agents, hydantoins, immunosuppressants, anti-protozoal agents, anti-thyroid agents, anxiolytic agents, sedatives, hypnotics, neuroleptics, beta blockers, cardiac inotropic agents, corticosteroids, diuretics, anti-parkinsonian agents, gastro-intestinal agents,

histamine receptor antagonists, keratolytics, anti-lipemic agents, anti-anginal agents, cox-2 inhibitors, leucotriene inhibitors, macrolides, muscle relaxants, nutritional agents, opioid analgesics, protease inhibitors, sex hormones, stimulants, muscle relaxants, anti-osteoporosis agents, anti-obesity agents, cognition enhancers, anti-urinary incontinence agents, nutritional oils, anti-benign prostate hypertrophy agents, essential fatty acids, non-essential fatty acids, or mixtures thereof.

4. The composition of claim 1 wherein the optional alkaline material is selected from lysine, arginine, sodium, potassium, calcium, magnesium or aluminum salts of phosphoric acid, carbonic acid or citric acid.

5. The composition of claim 1 wherein the optional alkaline material is selected from an aluminum hydroxide, calcium hydroxide, magnesium hydroxide, or magnesium oxide.

6. The composition of claim 1, wherein the water-insoluble binder is a polymethacrylic acid copolymer.

7. The composition of claim 1 wherein the enteric coating comprises a component selected from cellulose acetate phthalate, hydroxypropylmethyl cellulose phthalate, polyvinyl acetate phthalate, carboxymethylethylcellulose, or co-polymerized methacrylic acid/methacrylic acid methyl esters.

8. The composition of claim 2 wherein the enteric coating further comprises an inert processing aid.

9. The composition of claim 2 wherein the enteric coating further comprises from 10 to 80wt% by weight of the coating of an inert processing aid.

10. The composition of claim 1 wherein the surface-active agent is sodium lauryl sulfate.

11. The composition of claim 3 wherein the pharmaceutically active ingredient is an analgesic, anti-inflammatory agent, anti-coagulant, anti-psychotic, anti-epileptic, diuretic, anti-lipemics or pharmaceutically acceptable salts, isomers or derivatives thereof..

12. The composition of claim 3 wherein said analgesic is salicylic acid, indomethacin, ibuprofen, fenoprofen, oxaprozin, meclofenamate, mefanamic acid, naproxen, naproxen sodium, flubiprofen, indoprofen, ketoprofen, piroxicam, diclofenac, etodolac, ketorolac, or pharmaceutically acceptable salts, isomers or derivatives thereof.

13. The composition of claim 3 wherein said anti-convulsant is phenytoin, clonazepam, carbamazepam, valproic acid or pharmaceutically acceptable salts, isomers or derivatives thereof.

14. The composition of claim 3 wherein said antidiabetic is a biguanide, meglitinide, sulfonylurea, thiazolidinedione, or pharmaceutically acceptable salts, isomers or derivatives thereof.

15. The composition of claim 3 wherein said antilipemic is bile acid sequestrant, HMG-CoA reductase inhibitor, fibrate, fibric acid derivative, or pharmaceutically acceptable salts, isomers or derivatives thereof.

16. The composition of claim 3 wherein said diuretic is carbonic anhydrase inhibitor, thiazide, potassium sparing diuretic or pharmaceutically acceptable salts, isomers or

derivatives thereof.

17. The composition of claim 3 wherein said anti-histamine is loratadine, fexofenadine, certirizine, or pharmaceutically acceptable salts, isomers or derivatives thereof.

18. The composition of claim 3 wherein said anti-psychotic is benzodiazepine, an anti-anxiety agent, an antidepressant, a monamine oxidase inhibitor, a selective serotonin reuptake inhibitor, a tricyclic antidepressant, an antimanic agent, an antipanic agent, phenothiazine, or pharmaceutically acceptable salts, isomers or derivatives thereof.

19. The composition of claim 18 wherein said anti-psychotic is chlorpromazine, trifluprомazine, thioridazine, trifluoperazine, a barbiturate, phenobarbital, amobarbital, pentobarbital or pharmaceutically acceptable salts, isomers or derivatives thereof.

20. A oral controlled release pharmaceutical composition having a controlled release core, said core consisting essentially of:

a therapeutically effective amount of a pharmaceutically active ingredient, an optional surface active agent, an optional pharmaceutically acceptable alkaline agent, at least one water soluble binder and at least one water insoluble binder; wherein said controlled release is achieved through the use of said water soluble and water insoluble binders.

21. A method for manipulating bioavailability of a pharmaceutical dosage formulation comprising a core having powdered components and a coating, said method comprising the step of providing at least one water-insoluble binder and at least one water soluble binder in the core to control cohesiveness of powdered core

components upon disintegration of the core.

22. The method of claim 21, wherein the water-insoluble binder is a polymethacrylic acid copolymer.